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| APPLICATION NO. | | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|------|-------------|---------------------------------|-------------------------|------------------|
| 09/674,722 06/27/2001 | | 06/27/2001 | Alastair David Griffiths Lawson | 1300-1-007 | 4141 |
| 23565 | 7590 | 06/25/2003 | | | |
| KLAUBER | | | EXAMINER | | |
| 411 HACKENSACK AVENUE HACKENSACK, NJ 07601 | | | | DIBRINO, MARIANNE NMN | |
| | | | | ART UNIT | PAPER NUMBER |
| | | | | 1644 | 10 |
| | | | | DATE MAILED: 06/25/2003 | 10 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|---|---|---------------------------------|--|--|--|--|--|
| , | • | | | | | | |
| | Office Action Summary | 09/674,722 | LAWSON ET AL. | | | | |
| | Onice Action Summary | Examiner | Art Unit | | | | |
| | The MAILING DATE of this communication and | DiBrino Marianne | 1644 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 07 A | A <u>pril 2003</u> . | | | | | |
| 2a) <u></u> ☐ | This action is FINAL . 2b)⊠ Th | is action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | | | | | | | |
| , | Claim(s) <u>19-41</u> is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| • | Claim(s) is/are allowed. | | | | | | |
| · · · · · · · · · · · · · · · · · · · | Claim(s) is/are rejected. | | | | | | |
| · _ | Claim(s) is/are objected to. | | | | | | |
| • | Claim(s) <u>19-41</u> are subject to restriction and/or ion Papers | election requirement. | | | | | |
| · · · _ | The specification is objected to by the Examine | r. | | | | | |
| - | The drawing(s) filed onis/are: a)☐ accept | | miner. | | | | |
| ,_ | Applicant may not request that any objection to the | | | | | | |
| 11) 🔲 | The proposed drawing correction filed on | _ is: a)☐ approved b)☐ disappro | oved by the Examiner. | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) ☐ The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| * (| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachment(s) | | | | | | | |
| 2) Notic | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal I | (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | |

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DETAILED ACTION

1. Applicant's amendment filed 4/7/03 is acknowledged and has been entered.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 19-33, drawn to a chimeric receptor

Note Absent evidence to the contrary, each of the recited chimeric receptors is distinct since each ligand(s) to which each of said chimeric receptors is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 19-33 encompass hundreds of GROUPS, not species.

II. Claims 34-39, drawn to a nucleic acid sequence encoding a chimeric receptor, a plasmid comprising said nucleic acid sequence encoding said receptor

Note Absent evidence to the contrary, each of the nucleic acid sequences encoding the chimeric receptors/ plasmid comprising said nucleic acid sequence encoding said receptors is distinct since each ligand(s) to which each of said chimeric receptors is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 34-39 encompass hundreds of GROUPS, not species.

III. Claims 40 and 41, drawn to an effector cell containing a nucleic acid sequence encoding a chimeric receptor and/or expressing expressing the chimeric receptor.

Note Absent evidence to the contrary, each of the effector cells containing a nucleic acid sequence encoding the chimeric receptors is distinct since each ligand(s) to which each of said chimeric receptors is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 40-41 encompass hundreds of GROUPS, not species.

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3. The inventions listed as the Groups mentioned above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 19 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Gross et al (PNAS USA 86: 10024-10028, 1989, of record). Gross et al teach DNA coding for a chimeric receptor containing two or more independent polypeptide chains comprising in N- to C-terminus sequence (see entire article).

Therefore because claim 19 lacks an inventive step, the instant invention lacks Unity of Invention.

- 4. It is noted that the instant claims encompass a specific chimeric receptor, or DNA encoding said receptor or effector cell expressing said receptor consisting of numerous combinations as follows. Applicant is required to elect a specific chimeric receptor (I), nucleic acid sequence encoding a specific chimeric receptor (II), or a specific effector cell containing a nucleic acid sequence encoding a specific chimeric receptor or a plasmid comprising the said nucleic acid sequence and/or expressing a specific chimeric receptor (III), with a specific number of independent polypeptide chains comprising a specific extracellular ligand association domain (for example, CD29), a specific spacer domain (for example, a polypeptide comprising 20 to 100 amino acid residues), a specific transmembrane domain (for example, an oligo or polypeptide derived from all or part of the TCR alpha chain), a specific intracellular domain(s) (for example, a naturally occurring polypeptide signaling sequence that is all or part of the TCR zeta chain).
- 5. If Applicant elects the claims 34-39 (II), Applicant is further required to (1) elect a specific carrier or plasmid, for example, a viral vector or plasmid pHMF374 of Figure 3) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different and they are different vectors.

- 6. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.
- 7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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- 8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).
- 9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
- 10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
- 12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061. The examiner can normally be reached on Monday, Wednesday and Friday afternoons.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Marianne DiBrino, Ph.D.

Patent Examiner

Group 1640

Technology Center 1600

June 18, 2003

TECHNOLOGY CENTER 1600